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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/963,239	11/03/97	GOUGH E	13724-707 C

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EXAMINER	
PEFFLEY, M	
ART UNIT	**PAPER NUMBER**
3739	17

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/963,239	Applicant(s) GOUGH ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☒ Responsive to communication(s) filed on *21 April 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☒ The proposed drawing correction filed on *21 April 2000* is: a)☒ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Applicant's amendments and comments, received April 21, 2000, have been fully considered by the examiner. The following is a complete response to the April 21, 2000 communication.

Drawings

Applicant's new drawing, Figure 1b, is acknowledged and acceptable. It is noted that newly submitted Figure 1b is a figure from US Patent No. 5,536,267 which is incorporated in the instant application.

Specification

The amendment filed April 21, 2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the amendment to page 5, line 26 which inserts the brief description of newly added Figure 1b. This brief description indicates there is a rigid electrode advancement member. Neither the instant application, nor Serial No. 08/290,031 (now US Pat No. 5,536,267) incorporated by reference into the instant application, specifically disclose a "rigid electrode advancement member". It is suggested the term "rigid" be removed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 36 is objected to because of the following informalities: the term "to" following "member" in line 8 is extraneous. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-18, 33-35 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-18 and 33-35 recite the device is used in either a bipolar or a monopolar mode, which is unclear since there is insufficient means (i.e. an energy source) recited in the claims. Applicant must either positively recite the energy source, or amend the language of the rejected claims to indicate that the device is "adapted" to operate in a bipolar or monopolar mode.

Claims 37-39 are unclear with the phrase "electromagnetic energy source is delivered to the plurality of antennas". It appears as though "source" should be deleted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 and 15-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVeen et al ('276) in view of the teaching of Edwards et al ('675).

LeVeen et al discloses a device which comprises a trocar (502) and a multiple antenna ablation device (26) including three or more antennas (24) deployable from the trocar lumen in a lateral direction. Each of the antennas has an ablation surface, and the plurality of antennas are used to create an ablation volume of spheroid shape. The antennas are less rigid than the trocar, and the power range disclosed by LeVeen et al is within the range set forth by the applicant. Further, LeVeen et al teach that the device may be used in either a bipolar or a monopolar mode with the trocar serving as a possible return path.

The only feature not expressly taught by LeVeen et al is the energy delivery surface size which is "sufficient to create a volumetric ablation between the deployed antennas without impeding out a deployed antenna when 5-200 watts of electromagnetic energy is delivered" and the use of an impedance monitoring means. In as much as the LeVeen et al and the applicant's device appear very much similar, the examiner can see no reason why the LeVeen et al device would "impede out". More specifically, there is no specific disclosure in the applicant's specification of the particular size of the energy delivery surface which prevents this "impeding out" of the electrodes. Moreover, it appears one of ordinary skill in the art would obviously be capable of creating the proper energy surface area to prevent impeding out an antenna without undue experimentation.

Edwards et al teach that it is generally well known to monitor the impedance of a multiple electrode RF ablation device so as to avoid unwanted impedance levels (see column 13, lines 11-13). Such impedance monitoring and feedback means are

generally well known in the art. Edwards et al also disclose the use of sensors (i.e. temperature sensors) located on the electrodes and the sheath (see Abstract), as well as a means to provide a fluid to tissue.

Also, while LeVeen et al disclose the use of a trocar to introduce the multiple antenna ablation device, LeVeen et al fail to disclose the specific size of the trocar. The examiner maintains that use of any well known trocar size would have been an obvious design consideration dependent upon the particular procedure as well as the particular antenna device being used.

With respect to the newly added limitation of an antenna advancement member "sufficiently rigid to move in a longitudinal direction", the examiner maintains that the LeVeen et al "cable" is sufficiently rigid to simultaneously advance the antennas, particularly since this is the disclosure of the LeVeen et al reference.

To have provided the LeVeen et al device with an impedance monitoring and control means to control the delivery of energy to the electrodes to avoid "impeding out" the electrodes would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards et al ('675).

Response to Arguments

Applicant's arguments filed April 21, 2000 have been fully considered but they are not persuasive.

First, it is noted that applicants have filed no amendments and no argument with respect to the 35 USC 112, second paragraph rejection of the claims. This rejection is repeated and made final.

With respect to the drawing objection and 35 USC 112, first paragraph rejection made in the previous Office action, these issues are deemed obviated by applicant's amendments and comments. In particular, the claim language has been amended to remove the phrase "rigid antenna advancement member" and replace it with an antenna advancement member which is "sufficiently rigid to move in a linear direction....to simultaneously advance the three or more antennas from the trocar". The examiner agrees that there is proper support for this limitation in the specification, particularly in view of the new drawing figure.

The examiner maintains that the 35 USC 103 rejection is tenable, however, and the rejection is made final. First, the examiner maintains that the LeVeen et al device clearly has an antenna advancement member "sufficiently rigid" to simultaneously advance the antennas. The entire LeVeen et al disclosure indicates that the antennae may be simultaneously introduced into tissue. The "cable" or bundled proximal end of the wires is used to advance the electrodes, and this bundled proximal end is clearly sufficiently rigid to advance the electrodes from the trocar. Further, the examiner maintains that the use of a "cam" member (as illustrated in applicant's newly added Figure 1b) to advance electrodes is generally well known in the art. Column 7, lines 60-65 of US Patent No 5,536,267 (from which applicant's newly added Figure 1b is incorporated) clearly states that such cams are of conventional design and are well known in the art. In light of this disclosure, the examiner maintains that use of such a cam in the LeVeen et al device would clearly be obvious to one of ordinary skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on M-F (7:00-4:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda M Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
May 31, 2000